



# SCT

## SOCIETY FOR CLINICAL TRIALS

volume 20, number 2 | October 2009

# Newsletter

### SCT President's Corner

**By Colin Begg, President**



The Society is in a period of change. After the annual meeting in Atlanta in May, Fernley and Fernley, Inc. assumed the role of managing the organization, replacing the singlehanded efforts of Mary Burke, who retired after 20 years of exemplary service. At a special banquet in Atlanta, the long service of both Mary and Chris Donhauser was celebrated by a large collection of old friends and colleagues and former Officers. Chris's service as Treasurer has for many years kept our finances in order. I am delighted to inform you that Joe Collins was willing to assume the role of Treasurer, and his election was unanimously

approved by the Board at its July meeting.

In parallel with these changes, a committee headed by Dan Sargent worked diligently during the past year to rewrite our By-Laws and Constitution. The new By-Laws provide a simpler and more flexible set of rules for governance by our Officers and Board of Directors. When these changes were put to the vote, using a novel open electronic Special meeting of the Society on our new web site, they were approved by a unanimous vote.

As you are all aware, the Society exists in large part through the volunteer activities of members who participate in our various committees. Memberships of our committees are listed on our website ([www.sctweb.org](http://www.sctweb.org)). The following individuals have agreed to assume chairmanship of our standing committees: Simon Day will head chair the Program Committee for the forthcoming Baltimore meeting in May 2010; Barbara Tilley has assumed leadership of the Nominating Committee, charged with assembling nominees for President and the Board; Michael Hughes will chair the Student Scholarship Committee; Heidi Krause-Steinrauf has joined with Mark Espeland to share duties of chairing the Web Oversight Committee; and Chris Coffey will chair the Education Committee. We have also created an additional "Education" committee, the Educational Outreach Committee. This is headed by Bob Byington, and its mission will be to develop SCT educational activities that will take place outside of the typical forum of the Annual Meeting, the planning for which will remain the charge for the Education Committee.

A defining characteristic of the Society is its interdisciplinary flavor. Most professional societies are organized around a single discipline. By contrast our Society draws investigators and other professionals from various disciplines and settings including academia, industry, the non-profit sector, and government. What we all share is recognition of the crucial importance of well designed clinical trials in advancing the health of the public through high quality research. Our meetings provide a unique forum for interdisciplinary exchange among those committed to clinical trials research. Nonetheless, this interdisciplinary feature is an attribute we must continue to nurture. The Officers have been concerned for some time that we do not pay sufficient attention to engaging the interests of the disciplinary specialties among our membership. To address this issue, we have created 5 new sub-specialty committees and tasked them with identifying how

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### SCT President's Corner (continued)

to make the Society more attractive to the individual disciplines. These new committees and chairs are as follows: Information Technology Committee (Chair: Kristine Nelson); Clinical Research Associate Committee (Chair, Bev Koski); Industry/FDA Committee (Chair, Ivan Chan); Physician Trialist Committee (Chair, Yves Rosenberg); Statistician Committee (Chair Jen Bacik). If you have ideas that could make the Society more attractive for these individual disciplines, I'm sure our new chairs would be happy to hear them.

Another very important initiative has been the creation of our new website that went live during the Atlanta meeting. The Web Oversight Committee has been very busy this summer finding ways to use the framework of the new site to enhance the offerings for members. Some of the new features include access to our membership database, member profile editing, a greatly expanded set of links, access to materials from the Atlanta meeting, and provisions for electronic voting. Various other enhancements are under active consideration, and these are described in more detail later in this Newsletter.

Two years ago the Society engaged in the development of a strategic plan. This involved 5 key goals: development of an aggressive membership campaign; increasing the use of information technology, including the launch of a new web site; laying the foundation for a more active public role in policy debates relevant to trials; providing increased

educational opportunities; examining our mission to ensure our stability, growth and impact. We are currently planning a major membership drive this Fall, and the disciplinary committees I mentioned earlier will help to ensure that the drive targets all of our different types of members. We will need your help in passing on the word about the value of membership. Please take advantage of the printable SCT brochure on the web to give to colleagues who may benefit from membership in the Society. We need our membership to grow in order for the Society to be in a better position to have a major impact on the practice of clinical trials. We have responded to the second aim through the creation of the new website. We are working hard to increase educational opportunities through the activities of the new Educational Outreach Committee. Our new By-Laws and Constitution have clarified our mission, and the new management arrangement is designed to provide long-term stability. The one area where we have failed to make significant inroads is the development of an active role in public policy debates. We continue to seek member volunteers to help articulate the voice of the Society in the public arena.

We have much to do over the remainder of the year and we will need your support. Please let us know how the Society can serve your needs and do not hesitate to contact the Secretariat at Fernley and Fernley to provide suggestions.

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## SCT Website Committee Update

### **By Mark Espeland and Heidi Krause-Steinrauf, Web Oversight Committee Co-Chairs**

The SCT Website is undergoing serious enhancement to provide more information to members and to the clinical trials community as a dynamic resource. You'll want to check-out the **News and Events** on a regular basis to keep apprised of dates, meetings, educational courses and announcements of interest. The SCT leadership and Website Committee have been working with other organizations to provide reciprocal website links to facilitate networking and sharing of information. Click on **Sponsors and Links** to review recently added information on **Affiliate Sites** and **Useful Links for Clinical Trials**. If you have recommendations for new links, you can send them to the Website Committee.

A major effort is underway to provide educational materials, resources and other useful links relevant to clinical trials on the website. This exciting initiative will

facilitate establishing the SCT Website as a key resource for information on clinical trials. Many of the presentations from the 2009 SCT meeting in Atlanta are available to members via the **Members Only** section of the website (you'll need to login in to the Members only section for access). We are also pleased to inform you that abstracts for future SCT meetings will be available on the website (and searchable). There are plans to provide pre-recorded webcasts for key presentations from the 2010 meeting and to establish an on-line video and audio library.

To facilitate networking of Society membership, we are working to expand the functionality of the Members Directory to help you link with fellow members. Did you know you can update your own directory information via the Website? Also, don't forget to check-out the many opportunities posted on the **Job Board**. This is a great way to advertize a position or look for opportunities.

We welcome your ideas for continued enhancements to the Website to make it a key resource for SCT membership and the greater clinical trials community.

# Call for Abstracts and Invited Session Proposals – SCT 2010 Annual Conference

May 16 – 19, 2010

Baltimore Waterfront Marriott, Baltimore, MD, USA

## By Simon Day, 2010 Program Chair

The Program Committee is calling for proposals for the Contributed Paper, Posters and Invited Sessions as a means of engaging the Society's members in the annual meeting program development process.

### **Last Chance to Submit Invited Session Proposals**

An Invited Session typically brings together a set of speakers and discussants to present the latest results or emerging issues in an area of clinical trials research. This might include (but should not be limited to) statistical science, data management, study management, policy, regulation, etc. This year we would be particularly interested in sessions around the theme of "comparative effectiveness," but themes related to other topics will also be of interest. Indeed, the Program Committee encourages a variety of topics and issues in clinical trials research that would be of general interest to the Society's diverse and international membership. There are typically four simultaneous Invited Sessions during each of three 90-minute sessions for a total of up to 12 sessions.

Please submit proposals to the Program Chair, Simon Day, via the 2010 meeting page on the SCT website ([www.sctweb.org/meeting.cfm](http://www.sctweb.org/meeting.cfm)). Just follow the link to submit your session idea.

Proposals should include the following information:

- Your name, affiliation, contact address and e-mail address
- Suggested Invited Session title
- Brief description of the proposed Invited Session (1 paragraph)
- Suggested organizers, chair, speakers and discussant (which may include yourself)

### **Call for Contributed Paper/Poster Abstracts – Deadline: December 1**

Abstracts on topics of interest to the diverse membership of the Society are requested. These include issues related to the design, conduct, and analysis of clinical trials including but not limited to the following: statistical methodology; use and evaluation of technology in trial conduct; data management; quality assurance and monitoring; ethics, regulatory and safety; patient recruitment, enrollment and retention; study coordination and closeout.

Abstracts (300 word limit) should be as specific as possible to allow for adequate review and placement into an appropriate session. Preference will be given to abstracts that report completed investigation, analyses, designs, or methodological work over those that promise to carry out a project if accepted. Abstracts comprising only detailed results for individual trials, without general applicability, are more suitable for presentation at meetings of the appropriate specialty society.

Please submit abstracts to the Program Chair, Simon Day, by visiting the SCT website at [www.sctweb.org](http://www.sctweb.org) and following the link to submit your Abstract. Abstracts may appear in print exactly as submitted. All errors and misspelling are the responsibility of the author. The ENTIRE abstract, including title, author(s), institutional affiliation of FIRST author and text must not exceed 300 words. The abstract must contain, in the following order: (a) Title of paper in all capital letters with no abbreviation, (b) Full names of authors without degrees or titles, (c) Institutional affiliation, city, state or country of first author, and (d) Text of the abstract.

### **Student Scholarship Program – Deadline: December 1**

The Society intends to continue the Student Scholarship Program, started in 1985. Faculty advisors should bring the program to the attention of pre- and post-doctoral students including physicians and other health care professionals participating in clinical research training programs. A specific session will be held at the meeting for abstracts selected by the Student Scholarship Committee and successful candidates of this program will be funded to attend the meeting.

Abstracts for the Student Scholarship Program must be accompanied by a short manuscript (3-5 pages) and a letter from the student's advisor confirming status as a fulltime student. An abstract submitted for the Student Scholarship Program will not be considered for full conference presentation.

**Deadline:** Proposals for all abstracts and the must be submitted online by December 1, 2009.

For more details on submitting abstracts, Invited Session proposals, or participating in the Student Scholarship Program, visit the SCT website at [www.sctweb.org](http://www.sctweb.org)

The Program Committee looks forward to seeing you at the 2010 meeting in Baltimore.

# SCT 2010 Annual Conference Keynote Speakers

May 16 – 19, 2010

**Baltimore Waterfront Marriott, Baltimore, MD, USA**

The program for our forthcoming meeting in Baltimore is under development, and details will be distributed to the membership over the next few months. However, we are delighted to announce two dynamic keynote speakers:

## **Curtis Meinert Lecture: Joshua M. Sharfstein, MD**

Dr. Joshua M. Sharfstein was appointed by President Obama to be the FDA Principal Deputy Commissioner of the Food and Drug Administration. He served as Acting Commissioner for Food and Drugs from March 29 – May 25, 2009. From December 2005 through March 2009, Dr. Sharfstein was the Commissioner of Health for the City of Baltimore. In this position, he led efforts to expand literacy efforts in pediatric primary care, facilitate the transition to Medicare Part D for disabled adults, engage college students in public health activities, increase influenza vaccination of healthcare workers, and expand access to effective treatment for opioid addiction. Under his

leadership, the Baltimore Health Department and its affiliated agencies have won multiple national awards for innovative programs, and in 2008, Dr. Sharfstein was named a Public Official of the Year by *Governing Magazine*.

## **Founders Lecture: Richard Schilsky, MD**

Dr. Richard Schilsky is a major spokesman for the use of randomized clinical trials. From 1995-2009 he served as chairman of the Cancer and Leukemia Group B (CALGB), the largest and oldest cancer clinical trials group in the United States. Dr. Schilsky specializes in the treatment of gastrointestinal cancers and in the development of new cancer treatments. He is Professor of Medicine, and Section Chief for Hematology/Oncology at the University of Chicago.

## Save the Date!

**SCT 31<sup>st</sup> Annual Conference**

**May 16 – 19, 2010**

**Marriott Baltimore Waterfront**

**Baltimore, Maryland, USA**

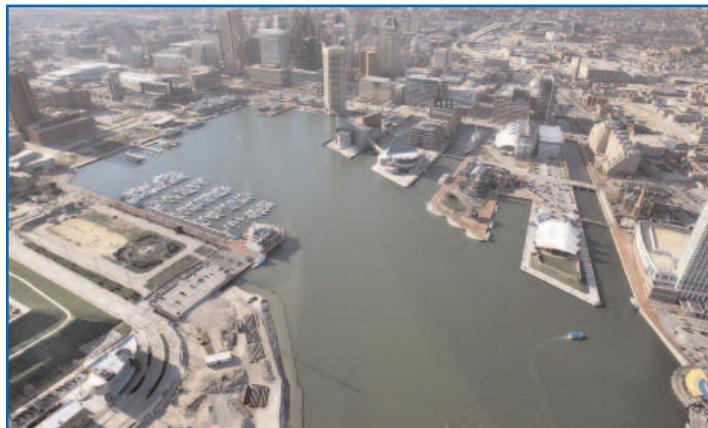
***Baltimore – The Inner Harbor and so much more!***

Baltimore is more than Maryland's largest city and economic hub. It is a colorful town bustling with culture, history, education and fun! The city is known for its beautiful harbor, but it also boasts charming neighborhoods, unique museums, exciting sports venues and diverse cuisine.

Located just 40 miles away from Washington, DC, Baltimore is well known to many in the clinical trials community, with the world-renowned Johns Hopkins Hospital to the east and the University of Maryland Medical Center to the west.

In addition, Baltimore holds a special place in American history, as site of the First Washington Monument, the first American Cathedral and the first public library, as well as several US Civil War landmarks and of course Fort McHenry, where Francis Scott Key penned the "Star Spangled Banner" during the War of 1812.

The picturesque Baltimore Harbor is a landmark attraction for shoppers, tourists, boaters, sports fans and locals, but Baltimore is also marked by unique architecture and rich



*Baltimore's Inner Harbor*

culture. A diversity of museum offerings include everything from the Baltimore Museum of Art, Maryland's largest art museum; to the American Visionary Art Museum, which displays original works of art created by self-taught artists. Of course the National Aquarium located on Baltimore Harbor is a premier attraction. Less well known but equally interesting are the Museum of Industry, the Great Blacks in Wax Museum, and the Fire Museum of Maryland.

An abundance of dining options can be found in downtown Baltimore, close to the SCT meeting host hotel – the Baltimore Waterfront Marriott. In addition to the world-famous Chesapeake Bay cuisine (crabcakes, anyone?), Baltimore offers every ethnic food imaginable, including fun and unique restaurants in the city's many eclectic neighborhoods.

*(Continued on next page)*

### **Baltimore: Easy to Get to and Worth the Trip!**

Baltimore is convenient from three nearby airports:

- Baltimore/Washington International Thurgood Marshall Airport – BWI – 12 miles
- Ronald Reagan Washington National – DCA – 45 miles
- Washington, DC/Dulles – IAD – 52 miles

The city is also convenient by Amtrak train from Boston, New York, Philadelphia, and DC.

When you are in the city, getting around is easy – it is a very walkable city and the metro subway, MARC train, cabs and water taxi are all convenient! In fact there is a water taxi stop located right by the meeting hotel – the Baltimore Waterfront Marriott.

### **Beautiful Baltimore Waterfront Marriott Welcomes SCT!**

The SCT host hotel, the Baltimore Marriott Waterfront is located in dynamic neighborhood of Harbor East – on the edge of Baltimore's historic Inner Harbor and near downtown. It offers stunning views and is just steps from restaurants and shops at the Inner Harbor, the National Aquarium, Maryland Science Center and USS Constellation. Guests also enjoy the hotel's close proximity

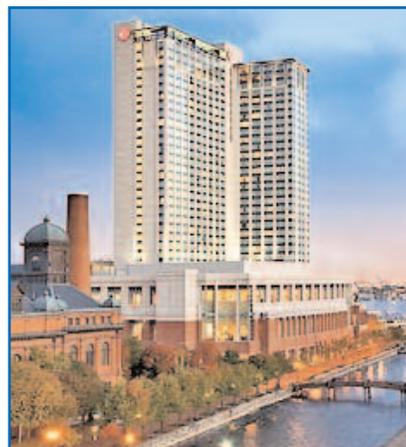
to the Convention Center, Camden Yards and the M&T Bank Stadium.

In addition to the meeting space that is perfect for the SCT meeting, this premier property features a swimming pool and fitness center. Each guestroom and suite features luxurious bed linens and hi-tech business amenities so guests can work or play in comfort.

SCT has secured a rate of \$215 at this beautiful property. There is also a block of government rooms available. It's easy to make your online hotel reservations now. Just visit the SCT website at [www.sctweb.org](http://www.sctweb.org) and click on the hotel reservations link.

For more information on the city of Baltimore and the Baltimore Waterfront Marriott, visit the SCT website – [www.sctweb.org](http://www.sctweb.org) – and click on the related links.

Watch the site and your e-mail for more information on the upcoming SCT meeting in Baltimore!



*Baltimore Waterfront Marriott*

## SCT/ImpACT Trial of the Year

### **By Dave Sackett, Trial of the Year Chair**

Each year the Society for Clinical Trials and Project ImpACT presents an award to the randomized clinical trial published in the previous year that best fulfills the following standards:

- It improves the lot of mankind.
- It provides the basis for a substantial, beneficial change in health care.
- It reflects expertise in subject matter, excellence in methodology, and concern for study participants.
- It overcomes obstacles in implementation.
- The presentation of its design, execution, and results is a model of clarity and intellectual soundness.

The first annual "SCT/ImpACT Trial of the Year" award was given in 2008 to Dr. Barbara Schmidt and her colleagues for their RCT of I-V caffeine for premature infants with apnea, a treatment that had been in irregular use for decades but never rigorously tested. In a challenging multicenter international trial of 2006 babies, they demonstrated not only reduced mortality from caffeine, but also reductions in cerebral palsy and developmental delay (*N Engl J Med* 2007;357:1893-1902).

The SCT/ImpACT Trial of the Year award for 2009 was presented at a special session of our Atlanta annual meeting to Dr. Christopher Bulpitt and his colleagues for their "Hypertension in the Very Elderly Trial (HYVET)." Carried out in 195 centers in 13 countries in Western and Eastern Europe, China, Australasia, and North Africa, they enrolled 3,845 women and men with persistent hypertension (systolic blood pressure of 160 mmHg or more) who were 80 years of age or older and were living independently. Over the next two years, the octogenarians randomized to mild blood pressure lowering drugs were a third less likely to suffer strokes, two-thirds less likely to go into heart failure, and one-fifth less likely to die than their fellow participants who had been randomized to placebos. These benefits began to appear within the first year of treatment, and there was no increase in drug side-effects (*N Engl J Med* 2008;358:1887-98).

### **Call for 2009 Trial of the Year Submissions**

We are now accepting nominations for the outstanding Trial of the Year published in 2009. The deadline for nominations is January 31, 2010, and the award will be presented at our annual meeting in Baltimore. Please go to our Society website or our Trial of the Year webpage ([www.projectimpact.info/sct/](http://www.projectimpact.info/sct/)) to nominate a trial you think best meets our standards.

## SCT Industry/FDA Membership Subcommittee Report

### by Ivan Chan, SCT Membership Subcommittee Chair

The SCT Industry/FDA Membership Drive Subcommittee is charged to make recommendations on ways to attract new members to join SCT from the industry and FDA sector. The committee has seven members including Greg Campbell (FDA), Li Chen (Amgen), Janna Scott (GSK), Arlene Reisman (Pfizer), Mary Varughee (Merck), Janet Wittes (Statistics Collaborative), and myself as the chair (Merck).

The committee has met over the summer and developed a set of preliminary recommendations. Some key components include

- Invite diverse speakers from industry, FDA and academia to participate in special sessions at the annual meeting. Topics of interests include DMC, interim analysis, adaptive design, safety monitoring, discussion of FDA guidance, and lessons learned.

- Conduct education workshops on FDA guidance, DMC/Interim analysis, CDISC, etc
- Plan virtual meetings (e.g. Webinar) on broad clinical trial topics such as fundamentals of clinical trials, DMC, trial design and conduct, SCT position papers, declaration of Helsinki, Good Clinical Trial Practice.
- Reach out to companies and the FDA to identify champions for SCT who can help disseminate the SCT information within their organizations.

The committee also discussed opportunities to provide networking activities at the annual meeting and co-sponsorship with other societies on educational or conference activities.

As we continue to develop the recommendations, any suggestions and comments are very welcome. Please feel free to send me an email ([ivan\\_chan@merck.com](mailto:ivan_chan@merck.com)) if you have a suggestion or would like to help identify a SCT champion for your organization.

## SCT Educational Outreach Committee

### By Bob Byington

As Colin Begg noted in the "President's Corner" section, one of the key goals for SCT is to provide increased educational opportunities for people involved in clinical trials. In partial response to this goal, the Education Committee has over the years organized fantastic, well-attended, and informative Preconference Workshops, usually held the day before our annual meetings. However, many people have noted it would be great if there were a way for our society to reach out beyond the annual meetings and to conduct and/or sponsor educational endeavors throughout the year in many different non-SCT venues. After all, there are many scientific/medical/policy/etc groups out there who could benefit from being exposed to what clinical trials are, what they could provide, and how they might be done. And this would be a great way for us to increase our visibility among people who do not yet belong to SCT.

In recognition and in response to this expanded perceived need, the Educational Outreach Committee was created this past year with the mission "to promote good clinical trial knowledge and practices by organizing educational sessions sponsored by the Society outside the venue of the Annual meeting." Current members include me, Denise Bonds, Domenic Reda, Anne Lindblad, Yves Rosenberg, Chris Coffey, Virginia Howard, and Kay Dickerson.

The Committee has hit the ground running! We have made contact with other societies and groups to offer our services and have received a number of nibbles and outright bites! For example, the Association for Research in Vision and Ophthalmology (ARVO) is having a three day course in Baltimore in December entitled "Principles and Concepts in Clinical Trials for Eye Researchers." Thanks to the efforts of Anne Lindblad, this course is now co-sponsored by SCT and SCT is providing some faculty members (see page 10).

And this is just one example of what we are working on now. In addition to trying to reach out and offer educational services to other specific associations and societies, our committee members are investigating other non-specific activities, such as developing free-standing SCT-sponsored courses in clinical trial theory and practice, developing an on-line course (or set of courses) that could be put on the SCT website, organizing clinical trial webinars, etc.

This is a great opportunity for us to promote SCT, to help people in other associations, and to develop closer professional ties with people and groups doing trials. If anyone has any ideas how we can expand our Educational mission, please drop me an e-mail ([bbyingto@wfubmc.edu](mailto:bbyingto@wfubmc.edu)).

## SCT Biostatistics Membership Subcommittee

### By Jennifer Bacik, SCT Membership Subcommittee Chair

The SCT Biostatistics Membership Drive Subcommittee was formed in June 2009 with two general goals: 1) Determine what makes SCT attractive to biostatisticians and 2) Brainstorm about changes SCT could implement to enhance its attractiveness.

In addition to myself, the other members of the committee are:

- Robert Anderson, University of Illinois at Chicago
- Susan Halabi, Duke University Medical Center
- Shelley Hurwitz, Brigham and Women's Hospital
- Maureen Maguire, University of Pennsylvania
- Tony Panzarella, Princess Margaret Hospital
- Matthew Sydes, MRC Clinical Trials Unit
- David Verbel, Eisai Medical Research

The committee met over the summer and has generated many good ideas on how to increase SCT's visibility within the biostatistics community. The following is a summary of our key ideas:

- Increase opportunities for networking at the Annual Meeting, including
  - Small group discussions in which a leader chooses a specific topic that forms the basis of an interactive discussion. This could take the form of a mentoring session in which a senior member of SCT provides guidance to junior members.
  - Allow time in the program for networking with others in the same discipline. Plan smaller sessions in which the presentations revolve

around a theme. Time is provided following the presentations for networking.

- Find ways to engage members between the Annual Meetings, by offering webinars and workshops in smaller venues, perhaps focused on a particular methodological or therapeutic area.
- Increase the amount of resources available on the Members Only Section of the Website. Make members want to log into the website to see what is new. Have the ability to search the Membership Directory by areas of interest, job description, zip code and committee membership. Include educational and reference materials especially for individuals who may be new to the clinical trials world.
- Have a more international focus and create opportunities for international participation.
- Have a presence on LinkedIn, Facebook and/or Twitter.
- Introduce a new series on the website, "Paper of the Month" where a key paper/finding is highlighted.
- Ensure that SCT Leadership attends the new member reception at the Annual Meeting and interacts with the new members to draw them into the society and keep them there.

The Biostatistics Membership Committee continues to brainstorm about ideas that would encourage new members to join SCT and keep current members coming back for more. Suggestions are welcome! If you would like to contribute an idea or a comment, please email me at [jbacik@emmes.com](mailto:jbacik@emmes.com).

## SCT Education Committee Update

### By Christopher S. Coffey, Education Chair

The SCT Education Committee for 2009-2010 is being chaired by Chris Coffey. Other committee members for this year include: Jeff Blume, Denise Bonds, Li Chen, Jodi DeStefano, Marta Gilson, Susan Halabi, Keri Hammel, Devin Hunt, John Lum, Oscar Moreno, Tom Moritz, Elizabeth Murphy, Kristine Nelson, Wendy Parulekar, Yves Rosenberg, Roberta Scherer, Elsayed Soliman, Cindy Stowe, Julie Weston, and Carole White. The primary function of the committee is to plan the pre-conference workshop program. These workshops are selected to appeal to the diverse backgrounds of SCT membership and include offerings in advanced statistical methods, information technology, trial and site management, and general design and conduct of clinical trials.

The committee is already hard at work planning pre-conference workshops for the 2010 meeting in Baltimore. The overall workshop program is selected to appeal to the diverse backgrounds of SCT membership. Individual workshop proposals may have broad appeal to the diverse membership of the society or may be focused towards specific interest groups in the society (i.e., clinical investigators, site coordinators, trial monitors, information technology specialists, or biostatisticians). We are eager to hear from members if they have any suggestions for potential workshops, particularly if you or someone you know is interested in presenting a workshop. In general, pre-conference workshops should be four hours long, although eight hour workshops will also be considered by the committee. If you have suggestions for a workshop, please contact Chris Coffey at [christopher-coffey@uiowa.edu](mailto:christopher-coffey@uiowa.edu).

## SCT IT Membership Subcommittee

### By Kristine Nelson, SCT Membership Subcommittee Chair

The SCT IT Membership Drive Subcommittee is brainstorming methods to encourage IT professionals associated with clinical trials to join SCT. The committee is composed of the following members:

- Adel Taweel from University of Birmingham, UK
- Brian Becker, Jaeb Center for Health Research, Florida
- Dianne Reeves, NIH, Maryland
- James Batchelor, University of Southampton, UK
- Scott Rushing, Wake Forest University, North Carolina

The committee has met four times and is recommending and spearheading the following:

- Increase IT offerings at the SCT annual conference to include IT issues such as security, software, data management and systems configuration

- Conduct at least 2 IT education workshops at the SCT annual conference
- Develop a web presence for sharing of ideas concerning IT issues we face in clinical trials
- Conduct a meet and greet time at the SCT annual conference to encourage connections and collaborations
- Identify an IT initiative within the SCT which can be offered as a solution to the issue of remembering multiple user names and passwords

The ideas and recommendations from this team continue to develop. If you are an IT professional within SCT please consider joining us on our journey of connecting and sharing ideas. We believe making a community of IT professionals, offering IT solutions, and sharing ideas will increase SCT visibility to the IT world of clinical trials. If you have suggestions or would like to join this team, contact Kristine Nelson at [knelson@emmes.com](mailto:knelson@emmes.com).

## Attention Educators:

## Don't Forget the SCT Student Scholarship Program!

### Deadline for submissions: December 1, 2009

All students enrolled in a degree program of an accredited college or university, post-doctoral fellows, or physicians enrolled in an accredited residency program are eligible and are invited to enter the SCT Student Scholarship competition.

Acceptable topics are clinical trial-related issues such as study design and data analysis; meta-analysis; medical, ethical or legal issues; data entry, management, and computing as it relates to clinical trials; review of the results or methods of a class of trials; or scholarship in the history of clinical trials. Results of particular clinical trials are of interest if they have broader implications for the design, conduct or analysis of other clinical trials which are addressed in the paper. Important applied papers are particularly encouraged.

Three winners will be named "Sylvan Green Scholars" and will be selected to present their papers at the 2010 Annual Conference in Baltimore. Their fees will be waived and their travel and living expenses for the meeting will be paid by the Society.

The Thomas C. Chalmers Student Scholarship Award and a \$500 cash prize will be given to the student judged to have the best paper.

**The deadline for submission of abstracts (with three-page short manuscript) is December 1, 2009.**

This is an excellent opportunity for your students! Encourage them to submit via the online abstract submission process on the website at [www.sctweb.org](http://www.sctweb.org) (in the section on the Annual Meeting).

## SCT Dates to Remember

- |   |  |
|---|--|
| <b>November</b> – Dues invoices will be mailed.                 | <b>January 15</b> – SCT Fellows Nomination deadline                |
| <b>November</b> – Ballots for 2010 elections will be mailed     | <b>January 31</b> – Trial of the Year submission deadline          |
| <b>December 1</b> – SCT Student Scholarship submission deadline | <b>May 16-19</b> – SCT Annual Conference, Baltimore, Maryland, USA |
| <b>December 1</b> – SCT Conference abstract submission deadline |  |

# Committee Seeking Nominations for the Honorary Title "Fellow of the SCT"

**By Barry R. Davis, SCT Fellows  
Committee Chair**

**Deadline January 15, 2010**

The Society established the title of "Fellow of the Society for Clinical Trials (FSCT)" in 2005 to honor past or current Society member who have made significant contributions to the advancement of clinical trials. This title is granted to a number of society members each year at the Annual Meeting. The members of the 2009 Fellows class (inducted in May in St. Louis) were Joseph Collins, Frederick Ferris, Mary Foulkes, Jennifer Gassman, Edmund Gehan, Kuang-Kuo "Gordon" Lan, James Neaton, Steven Piantadosi, Sara Pressel, and David Sackett. A complete list of all the Fellows can be found at [www.sctweb.org/committees.cfm](http://www.sctweb.org/committees.cfm).

We are now seeking nominations for the Class of 2010. Candidates for this honor must have been an SCT member for at least five of the last 10 years or for a total of at least 10 years. Each nominee will be evaluated by the Committee on the basis of contributions to the advancement of clinical trials in one or more of the following areas:

- Methodologic development
- Coordination, conduct, or leadership of individual clinical trials
- Education
- Ethics
- Promotion of a better understanding by the general public or the importance of randomized clinical trials
- Service to the Society

The 2010 Committee on Fellows is currently being established and will be announced in the next newsletter. Any member of the Society may nominate a candidate. To do so, please assemble the following materials:

- Candidate's current curriculum vitae
- Three or more letters of support of the nomination from individuals qualified to describe the candidate's contributions to the Society. At least two of the letters should be from individuals at an institution, agency, or organization other than the candidate's.

Nomination packages may be submitted by email, fax, courier, or post to:

Barry R. Davis, MD, PhD  
SCT Committee on Fellows  
Coordinating Center for Clinical Trials  
University of Texas School of Public Health  
1200 Herman Pressler St. E-809  
Houston, TX 77030-3900 USA  
1-713-500-9530 (fax)  
[barry.r.davis@uth.tmc.edu](mailto:barry.r.davis@uth.tmc.edu)

**All nominations should be received no later than January 15, 2010**, for candidates to be considered for induction in 2010. Please send an email message of the nominee's name before preparing the package (to prevent dual work) and whenever materials are being sent via courier, fax or post.

## Save the Date for Future SCT Meetings:

May 15-19, 2011, Hyatt Regency Vancouver

May 20-23, 2012, Hyatt Regency Miami

## Notes from the Editor



If you would like to join the SCT or learn more about participating in upcoming meetings, visit the SCT website at [www.sctweb.org](http://www.sctweb.org) or contact headquarters at 215/564-3484 or [sct@fernley.com](mailto:sct@fernley.com).

If you have suggestions for this newsletter, contact SCT Newsletter Editor Christine Opiela at Fernley & Fernley, Inc. – 215/564-3484 or [copiela@fernley.com](mailto:copiela@fernley.com).

# How to Set Up and Manage a Clinical Trials Site

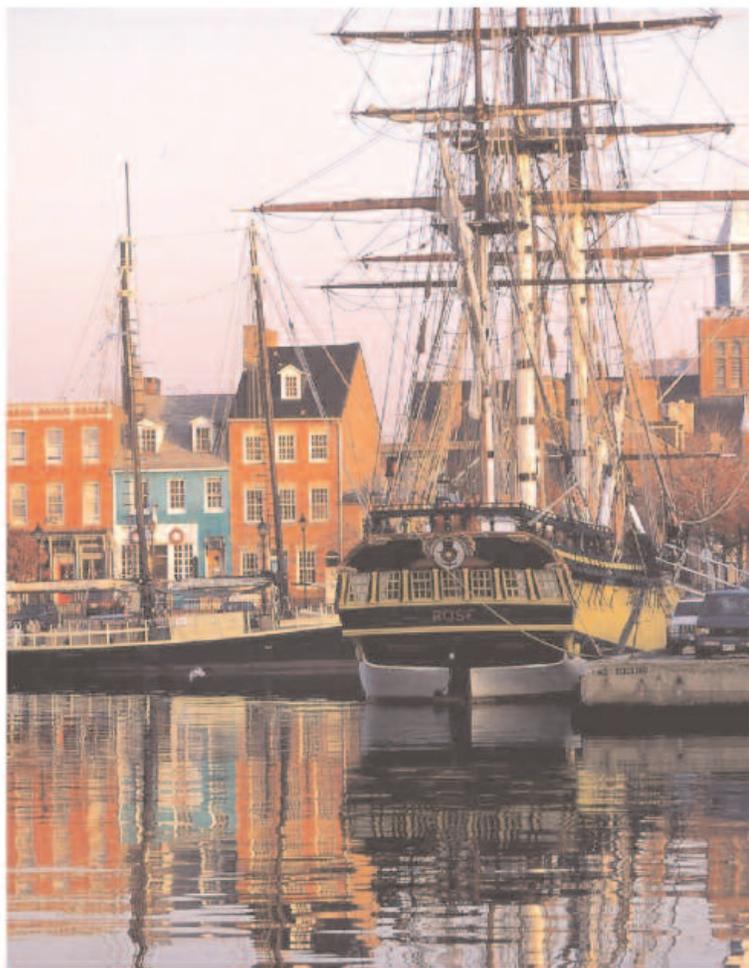
October 23, 2009, 4-9pm  
San Francisco, CA  
(the day before the AAO Meeting)



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